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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,002	10/24/2003	Mike West	028193-9025-04	2470

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EXAMINER
LIN, JERRY

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/692,002	WEST ET AL.
	Examiner	Art Unit	
	JERRY LIN	1631	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>28 February 2008</u>.

2a)☐ This action is **FINAL**.　　　2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>18-25</u> is/are pending in the application.

　　4a) Of the above claim(s) <u>19-23</u> is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>18,24 and 25</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

　　Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

　　Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

　　a)☐ All　b)☐ Some * c)☐ None of:

　　　1.☐ Certified copies of the priority documents have been received.

　　　2.☐ Certified copies of the priority documents have been received in Application No. _____.

　　　3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

　　* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1.   A request for continued examination under 37 CFR 1.114, including the fee set

forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this

application is eligible for continued examination under 37 CFR 1.114, and the fee set

forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action

has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on

December 28, 2007 has been entered.

Applicants' arguments, filed December 28, 2008, have been fully considered and

they are not deemed to be persuasive. The following rejections are reiterated. They

constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 18, 24, and 25 are under examination.

Claims 19-23 are withdrawn.

Claim Rejections - 35 USC § 112, 2nd Paragraph

2.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly
claiming the subject matter which the applicant regards as his invention.

Claims 18, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention.

Claim 18 recites the limitation "the statistical prediction" in line 2. There is

insufficient antecedent basis for this limitation in the claim. This limitation does not

appear previously in the instant claims. Claims 24 and 25 are rejected for depending

from claim 18.

Claim Rejections - 35 USC § 101

3.   35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
> matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the
> conditions and requirements of this title.

4.   Claim 18, 24, and 25 are rejected under 35 U.S.C. 101 because the claimed

invention is directed to non-statutory subject matter.

The instant claims are drawn to a computer based model of a classification tree.

However, a computer model of a classification tree is a form of data. Data does not fall

within any of the statutory classes of a process, machine, manufacture, or composition

of matter in 35 U.S.C. 101. Thus, the instant claims are non-statutory.

Response to arguments

5.   Applicants have responded to this rejection by amending the claim to include the

limitation of "computer based system." However, a computer based system, may be

drawn to a computer model. As explained above, a computer model does not fall within

any of the statutory classes and is non-statutory.

Claim Rejections - 35 USC § 103

6.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of

the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

7.   Claims 18, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Buntine (Statistics and Computing (1992) Volume 2, pages 63-73) in view of Veer

et al. (Nature (January 2002) Volume 415, pages 530-536).

The instant claim is drawn to a classification tree model incorporating Bayesian

analysis where the tree model comprises one or more nodes representing metagenes

(i.e., expression patterns of a set of genes) predictive of lymph node metastasis and

one or more nods representing risk factors.

Regarding claim 18, Buntine teaches a general classification tree model with

Bayesian analysis for the statistical prediction of binary outcomes (abstract; page 63)

where binary outcome is a clinical state, physiological state, a physical state, disease

state, or a risk group (for example, pregnant or not pregnant in Figure 1) (page 63, right

column; Figure 1); where the data is biological data (i.e. medical data) (page 63, right

column; Figure 1; page 66, left column 2nd full paragraph from the bottom).

      However, Buntine does not teach where the tree model has one or more nodes

representing metagenes predictive of lymph node metastasis.

      Regarding claim 18, Veer et al. teaches using data representing metagenes (the

expression patterns of a set of genes) predictive of lymph node metastasis in a

classification scheme to predict clinical outcomes (pages 531-533).

      Regarding claims 24 and 25, Veer et al teach where the clinical risk factor is

hormone receptor status (page 530, right column; page 534, right column) and an

outcome is tumor recurrence (e.g. prognosis of recurring tumors) (page 534, left

column).

      Buntine teaches a generic method of generating a classification tree model with

Bayesian analysis. According to Buntine, his method may be used for a variety of

different types of data, including biological data. Veer et al. teaches that using

metagene expression pattern data improves the prediction of clinical outcomes of breast

cancer. One of ordinary skill in the art would have used the metagene expression

pattern data as the biological data in Buntine's classification tree model. Thus, the

claim would have been obvious because the substitution of one known element for

another would have yield predictable results to one of ordinary skill in the art at the time

of the invention.

Response to Arguments

8.   Applicant have responded to this rejection by stating that Veer et al. do not teach

using one or more nodes representing clinical risk factors and a set of genes that are

predictive of lymph node metastasis. The Examiner disagrees. Veer et al. teach that

the genes expression data is combined with good versus poor prognosis patients.

Classification via good or poor prognosis patients may be considered clinical risk factors

(page 533).

        Applicants also state that Buntine discloses that the factors contributing to

prediction accuracy are unclear. Although Buntine believes more research into

Bayesian analysis is needed to determine the factors contributing to prediction

accuracy, Buntine is not suggesting that the using Bayesian analysis does not have

prediction accuracy. Buntine states, "In general, Bayesian option trees and averaging

yielded superior prediction accuracy. It was always competitive and usually superior to

the other algorithms." (page 72, left column). Give this statement, one of ordinary skill

in the art would expect that using Bayesian analysis would yield superior prediction

accuracy, even if the factors contributing to the accuracy are unclear.

                                    Contact Information

        Any inquiry concerning this communication or earlier communications from the

examiner should be directed to JERRY LIN whose telephone number is (571)272-2561.

The examiner can normally be reached on 7:00-5:30pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Examiner, Art Unit 1631
5/19/2008